

PCT 10/544213

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PCT 21346	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2004/008828	International filing date (<i>day/month/year</i>) 23 March 2004 (23.03.2004)	Priority date (<i>day/month/year</i>) 27 March 2003 (27.03.2003)	
International Patent Classification (IPC) or national classification and IPC A01N 43/42, A61K 31/44			
Applicant MERCK & CO. INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 01 October 2005 (01.10.2005) Authorized officer <p style="text-align: center;">Yolaine Cussac</p> Telephone No. +41 22 338 70 80
---	---

Form PCT/IB/373 (January 2004)

BEST AVAILABLE COPY

From the
INTERNATIONAL SEARCHING AUTHORITY

PATENT COOPERATION TREATY

To:
MATHEW A. LEFF
MERCK & CO., INC.
126 EAST LINCOLN AVENUE
RAHWAY, NJ 07065-0907

PCT

RECEIVED
10 OCT 2004

WIPO PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference		Date of mailing (day/month/year)
PCT 21346		07 OCT 2004
FOR FURTHER ACTION See paragraph 2 below		
International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US04/08828	23 March 2004 (23.03.2004)	27 March 2003 (27.03.2003)
International Patent Classification (IPC) or both national classification and IPC		
IPC(7): A01N 43/42; A61K 31/44 and US Cl.: 514/300, 301, 302, 303, 312; 546, 116, 118, 113, 135		
Applicant		
MERCK & CO., INC.		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Vickie Kim <i>J. Roberts</i> Telephone No. 571-272-1600
--	---

Form PCT/ISA/237 (cover sheet) (January 2004)

BEST AVAILABLE COPY

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/08828

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/08828

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-26 YES

Claims NONE NO

Inventive step (IS)

Claims 1-26 YES

Claims NONE NO

Industrial applicability (IA)

Claims 1-26 YES

Claims NONE NO

2. Citations and explanations:

Claims 1-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed invention that is directed to powder formulation for reconstitution comprising 3-[5-(4-methanesulfonyl-piperazin-1-ylmethyl)-1H-indole-2-yl]-1H-quinolin-2-one, as an active agent and filler, and the use thereof. US6306874 teaches novel compounds (e.g. 3-[5-(4-methanesulfonyl-piperazin-1-ylmethyl)-1H-indole-2-yl]-1H-quinolin-2-one) that inhibit, regulate and modulate tyrosine kinase signal transduction, compositions and the use thereof. However, it fails to teach a formulation adapted for reconstitution which enhances the stability and therapeutic efficacy of the said compound and their medical uses. Thus, the claimed invention is considered to be patentably novel and distinct over the prior art of the record.

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus the claimed invention improves industrial applicability because the subject matter claimed can be made or used in industry.